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EXAMINER	
FORMAN, BETTY J	

ART UNIT	PAPER NUMBER
1634	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/038,284	EHRICHT ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *26 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19 and 25-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19 and 25-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 26 May 2006 has been entered.

Status of the Claims

2. This action is in response to papers filed 26 May 2006 in which claims 1, 25-26, 44 and 46 were amended. All of the amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 24 June 2005 uner 35 U.S.C. 112, first paragraph, written description withdrawn in view of Applicant's comments on pages 9-10 of the response. The previous rejections under 35 U.S.C. 102 and 103, are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed but are deemed moot in view of the amendments, withdrawn rejections and new grounds for rejection. New grounds for rejection are discussed.

Claims 1-19 and 25-47 are under prosecution.

Claim Rejections - 35 USC § 102/103

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent

> or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1, 2, 4, 5, 8-10, 12, 14, 15, 17-19, 25-30, 32, 34-36, 39-43 rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Woudenberg et al (U.S. Patent No. 6,126,899, filed 2 April 1997).

Regarding Claim 1, Woudenberg et al disclose a device comprising a chamber body containing an optically permeable zone of detection (#180, Column 11, lines 11-25 and Fig. 6-9) and an optically permeable support (Column 12, lines 4-10) on which the body is sealingly placed to form a capillary gap (#164) wherein the gap forms a single reaction chamber adapted to amplify and characterize nucleic acids (Column 2, lines 32-46 and Column 3, lines 27-46).

Woudenberg et al further teach the device wherein the cavity includes a capillary gap between the support and detection area and a gas reservoir laterally offset from and in liquid communication with the capillary gap (Column 8, lines 16-38; Column 14, lines 47-56 and Fig. 9, #166) and an inlet by which liquid is introduced into the cavity (#162). Woudenberg et al also teach the gas reservoir collects gas from the capillary gap and is one to five times greater in volume that that capillary gap (Column 8, lines 32-38).

The preceding rejection is based on judicial precedent following In re Fitzgerald, 205 USPQ 594 because Woudenberg et al is silent with regard to the height of the capillary gap relative to the height of the gas reservoir. However, the height relationship recited in the

instant claims is deemed to be inherent in the capillary and gas reservervior volumes taught by Woudenberg et al because while, the reference does not specifically teach the height of the gas reservoir and/or capillary, the reference specifically teaches that the volume of the gas reservoir is one to five times larger than the capillary gap (Column 8, lines 32-38). Furthermore, Woudenberg et al teach the gas reservoir is used to remove residual gas from the capillary gap (Column 8, lines 28-30). Because gas rises and because the gas reservoir of Woudenberg is one to five times larger than the capillary gap, the height of the gas reservoir would be higher than that of the capillary.

Alternatively, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to provide the gas reservoir of Woudenberg et al with a height greater than that of the capillary for the obvious benefit of facilitating removal of gas (which inherently rises) from the capillary gap as they desire.

The burden is on applicant to show that the claimed relative height is either different or non-obvious over that of Woudenberg et al.

Regarding Claim 2, Woudenberg et al disclose the device further comprising means connected with the chamber for rapid temperature control (Column 3, lines 53-64).

Regarding Claim 4, Woudenberg et al disclose the device wherein the optically permeable zone includes detection spots (#108 or 168) wherein the temperature means are configured such that transparency of the chip is unaffected i.e. a signal is measured at timed intervals during the reaction which could only happen if the transparency remains unaffected (Column 21, lines 29-35).

Regarding Claim 5, Woudenberg et al disclose the device wherein the temperature adjustment means comprise micro-structured heating elements e.g. resistive tracings (Column 21, lines 47-54).

Regarding Claim 8, Woudenberg et al disclose the device wherein the support and body consist of glass, synthetic material or optically permeable synthetic material (Column 11, lines 13-20).

Regarding Claim 9, Woudenberg et al disclose the device wherein the support consists of a thermally conducting material (Column 11, lines 26-29).

Regarding Claim 10, Woudenberg et al disclose the device wherein the chip consists of glass, quartz or silicon (Column 11, lines 13-30).

Regarding Claim 12, Woudenberg et al disclose the device wherein the body includes an inlet (sample inlet #102/162) and outlet (vacuum port #106/216) spatially separate from each other (Fig. 6/9).

Regarding Claim 14, Woudenberg et al disclose the device wherein the body and support are sealingly and unrealeasably connected by adhesive (Column 12, line 58-Column 13, line 18).

Regarding Claim 15, Woudenberg et al disclose the device wherein the detection area is configured in the form of spots (#108 or 168) having nucleic acid probes immobilized i.e. pre-loaded reagents (e.g. nucleic acid probes or primes) are dried thereby immobilized to the detection spot (Column 16, lines 8-20 and Column 19, lines 45-Column 20, line 7).

Regarding Claim 17, Woudenberg et al disclose the device wherein the detection area is configured in the form of spots (#108 or 168) having peptide or proteins i.e. preloaded polymerase (Column 16, lines 13-15).

Regarding Claim 18, Woudenberg et al disclose the device wherein the gap is configured to allow optical or spectroscopy detection (Column 20, lines 10-23).

Regarding Claim 19, Woudenberg et al disclose the device is adapted to allow various forms of detections via optical and non-optical methods (Column 20, lines 10-13). The instantly recited "by a silver precipitation reaction" does not describe or define a structural component of the device. Because the recitation "by a silver precipitation reaction" does not

describe or define additional structural components of the device, the device of Woudenberg et al is encompassed by the instantly claimed device.

Regarding Claim 25, Woudenberg et al disclose a device comprising a chamber body (#180, Column 11, lines 11-25 and Fig. 6-9), chamber support (#164, Column 12, lines 4-10) and a capillary gap between the body and support wherein the gap forms a single reaction chamber adapted for reaction and characterization nucleic acids (Column 2, lines 32-46 and Column 3, lines 27-46).

Woudenberg et al further teach the device wherein the cavity includes a capillary gap between the support and detection area and a gas reservoir laterally offset from and in liquid communication with the capillary gap (Column 8, lines 16-38; Column 14, lines 47-56 and Fig. 9, #166) and an inlet by which liquid is introduced into the cavity (#162). Woudenberg et al also teach the gas reservoir collects gas from the capillary gap and is one to five times greater in volume that that capillary gap (Column 8, lines 32-38).

The preceding rejection is based on judicial precedent following In re Fitzgerald, 205 USPQ 594 because Woudenberg et al is silent with regard to the height of the capillary gap relative to the height of the gas reservoir. However, the height relationship recited in the instant claims is deemed to be inherent in the capillary and gas reservervior volumes taught by Woudenberg et al because while, the reference does not specifically teach the height of the gas reservoir and/or capillary, the reference specifically teaches that the volume of the gas reservoir is one to five times larger than the capillary gap (Column 8, lines 32-38). Furthermore, Woudenberg et al teach the gas reservoir is used to remove residual gas from the capillary gap (Column 8, lines 28-30). Because gas rises and because the gas reservoir of Woudenberg is one to five times larger than the capillary gap, the height of the gas reservoir would be higher than that of the capillary.

Alternatively, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to provide the gas reservoir of Woudenberg et al with a height

greater than that of the capillary for the obvious benefit of facilitating removal of gas (which inherently rises) from the capillary gap as they desire.

The burden is on applicant to show that the claimed relative height is either different or non-obvious over that of Woudenberg et al.

Regarding Claim 26, Woudenberg et al disclose the device wherein the body contains an optically permeable chip (#180, Column 11, lines 11-25; Column 12, lines 4-10; and Fig. 6-9).

Regarding Claim 27, Woudenberg et al disclose the device wherein the detection area includes immobilized probes within the gap i.e. pre-loaded reagents (e.g. nucleic acid probes or primers) are dried thereby immobilized to the detection spot (Column 16, lines 8-20 and Column 19, lines 45-Column 20, line 7).

Regarding Claim 28, Woudenberg et al disclose the device wherein the probes include nucleic acids (Column 16, lines 8-20 and Column 19, lines 45-Column 20, line 7).

Regarding Claim 29, Woudenberg et al disclose the device wherein the detection area is optically permeable (e.g. Column 12, lines 4-10).

Regarding Claim 30, Woudenberg et al disclose the device wherein the gap is temperature adjustable and flow-controllable (i.e. sample distribution network) (Column 13, lines 19-27 and 54-64).

Regarding Claim 32, Woudenberg et al disclose the device wherein the temperature adjustment includes microstructured temperature sensors i.e. temperature feedback (Column 26, lines 10-13).

Regarding Claim 34, Woudenberg et al disclose the device wherein the optically permeable material is polycarbonate or polystyrene (Column 10, lines 662-65 and Column 11, lines 13-20).

Regarding Claim 35, Woudenberg et al disclose the device further comprising an additional sealing surface i.e. inlet seal (Column 14, lines 56-63).

Regarding Claim 36, Woudenberg et al disclose the device wherein the nucleic acids are DNA or RNA (Column 15, lines 25-38).

Regarding Claim 39, Woudenberg et al disclose the device wherein the optical detection includes at least one of transmitted-light fluorescence measurement, dark field fluorescence measurement, confocal fluorescence measurement, reflected-light fluorescence measurement, photometry and differential photometry (Column 20, lines 13-23).

Regarding Claim 40-43, Woudenberg et al disclose the device wherein characterization (i.e. detection) is performed during reaction (i.e. at selected time points) and therefore, "almost" simultaneously as claimed (Column 21, lines 29-35). Woudenberg et al further teach various reactions are performed within the chamber e.g. PCR, ligation, primer extension and etc (Column 3, lines 28-38). The instantly claimed "adapted to perform" does not define or describe structural elements of the device. Because Woudenberg et al specifically teach the claimed structural elements, because Woudenberg et al teach various reactions performed within the device, and because the instant claims do not define further structural components of the device, Woudenberg et al teach the device as claimed.

Response to Arguments

6. Applicant asserts that Woudenberg et al do not teach the claimed cavity that includes both a capillary gap and gas reservoir that is laterally offset from and in liquid communication with the capillary gap. Applicant argues that even if the vacuum port or gas reservoir is interpreted as a gas reservoir, Woudenberg does not teach them included in a cavity with the capillary gap. The argument has been considered but is not found persuasive because the Woudenberg et al specifically teaches a "reservoir" for collecting "gas" from the reaction chambers (Column 14, lines 53-56). Furthermore, Woudendberg teaches the reservoir is within the same cavity as the capillary gap all of which is connected by channels (#170) within the cavity formed between the cover (#180) and base (#161) as illustrated (Fig. 9). Applicant appears to be asserting that the instantly claimed "single chamber" differs from the multiple

chambers (#168) of Woudenberg. However, the instant claims do not define over the chamber of the reference because the open claim language "comprising" encompasses additional elements. Furthermore, the array of chambers taught by the reference together form a single chamber formed between the cover (#180) and base (#161) as illustrated (Fig. 9). For these reasons, the reference teaches the device as claimed.

7. Claims 1-5, 8-10, 12-15, 17-19, 25-36 and 38-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lipshutz et al (U.S. Patent No. 5,856,174, issued 5 January 1999)) in view of Sugarman et al (U.S. Patent No. 5,222,808, issued 29 June 1993).

Regarding Claim 1, Lipshutz et al disclose a device for duplicating and characterizing nucleic acids, the device comprising, a chamber body containing an optically permeable chip (i.e. glass, Column 14, line 35-Column 15, line 29) having a detection area having an optically permeable zone of detection (i.e. transparent window, Column 19, lines 20-29) adapted to immobilize nucleic acids, peptides or proteins e.g. polymerase enzymes (Column 8, lines 23-42) wherein the chip is placed and sealed on an optically permeable chamber support (i.e. planar glass support, Column 15, lines 9-34) so that a sample chamber having a capillary gap is formed between the chamber support and the detection area (i.e. the reaction chamber is manufactured into the surface of a first planar member which is then covered by a second planar member providing a gap between the first and second planar members, Column 15, lines 9-34) wherein the gap (chamber) is provided with amplification and characterization means i.e. temperature control means for thermocycling and pcr amplification whereby nucleic acids are amplified and characterized via amplification (Column 19, lines 1-15 and Column 24, line 34-Column 25, line 41). Lipshutz et al further teach the chamber comprises a gas vent

within the chamber and in fluid communication with the chamber (Column 17, lines 28-32) but does not teach the vent is laterally offset and having a greater height.

However, Sugarman et al teach a reaction chamber having a gas reservoir (#59 and #60) within the capillary gap, in fluid communication with the gap and laterally offset from the reaction chamber and having a height that is greater than that of the capillary gap (Fig. 2). Sugarman et al further teach the gas reservoir, as constructed, provide for introduction of fluids into the capillary space and gases out of the space to provide "complete mixing" (Column 2, line 66-Column 3, line 14). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the vent of Lipshutz et al with the laterally offset vent of Sugarman et al. One of ordinary skill in the art would have been motivated to do so for the expected benefit of providing complete mixing in a simply designed chamber as taught by Sugarman et al (Column 2, line 66-Column 3, lines 14).

Regarding Claim 2, Lipshutz et al disclose the device comprising temperature adjustment means connected to the chamber support and permit rapid temperature control of the gap i.e. provide conditions for PCR amplifications within the chamber (Column 19, lines 1-15 and Column 24, line 34-Column 25, line 41).

Regarding Claim 3, Lipshutz et al disclose the device wherein the temperature adjustment means are situated on the side of the chamber support facing the chamber body (Column 24, lines 34-63 and Fig 2B #128).

Regarding Claim 4, Lipshutz et al disclose the device wherein the optically permeable zone of detection includes detection spots (i.e. transparent window for observation of a "particular analysis", Column 19, lines 20-29) and wherein the temperature adjustment means are configured such that the optical transparency of the chip remains unaffected i.e. the "heater insert" is disposed on the side of the chamber thereby not affecting the transparency of the chip Fig 2B #106/112 (Column 24, lines 34-63 and Fig 2B #128).

Regarding Claim 5, Lipshutz et al disclose the device wherein the temperature adjustment means comprises micro-structured heating elements i.e. nickel-chromium film (Column 24, lines 53-59) and micro-structured temperature sensors (Column 25, lines 7-41).

Regarding Claim 8, Lipshutz et al disclose the device wherein the chamber support and body consist of glass ,synthetic material or optically permeable synthetic materials e.g.nylon, Teflon, topaz, polycarbonate, polystyrene, PMMA and/or polymethane, ethyl acrylate (Column 15, lines 26-58).

Regarding Claim 9, Lipshutz et al disclose the device wherein the chamber support consists of thermally conducting material i.e. the heating/cooling means are embedded within the support which then conducts the heat to the reaction chamber (Column 27, lines 37-47 and Fig. 8 #806).

Regarding Claim 10, Lipshutz et al disclose the device wherein the chip consists of optically permeable materials e.g. glass (Column 15, lines 25-29).

Regarding Claim 12, Lipshutz et al disclose the device further comprising an inlet and an outlet spatially separate from each other i.e. fluid channel #212 is an inlet for reaction chamber #214 and fluid channel #216 is an outlet for reaction chamber #214 (Fig. 3 and Column 16, lines 12-18).

Regarding Claim 13, Lipshutz et al disclose the device wherein the inlet and outlet are arranged unilaterally and are separated by a gas reservoir nose i.e. gas permeable membrane to allow escape of accumulated gas (Column 17, lines 28-38)

Regarding Claim 14, Lipshutz et al disclose the device wherein the chamber body is sealingly and unreleasbaly connected with the chamber support with an adhesive or welding connection (Column 15, lines 20-29)

Regarding Claim 15, Lipshutz et al disclose the device wherein the detection area is configured in the form of spots onto which nuclei acid probes are immobilized i.e. positionally distinct probes (Column 9, lines 30-35 and Column 9, lines 20-29).

Regarding Claim 17, Lipshutz et al disclose the device wherein the detection area is configured in the form of spots onto which probes in the form or peptides or proteins are immobilized e.g. polymerase enzymes (Column 8, lines 23-42).

Regarding Claim 18, Lipshutz et al disclose the device wherein the capillary gap is adapted to allow characterization by optical detection (i.e. transparent window for observation of a "particular analysis", Column 19, lines 20-29)

Regarding Claim 19, Lipshutz et al disclose the device is adapted to allow characterization (i.e. transparent window for observation of a "particular analysis", Column 19, lines 20-29). The instantly recited "by a silver precipitation reaction" does not describe or define a structural component of the device. Lipshutz et al teach the device is adapted for characterization via observation through a transparent window, and because the recitation "by a silver precipitation reaction" does not describe or define additional structural components of the device, the device of Lipshutz et al is encompassed by the instantly claimed device.

Regarding Claim 25, Lipshutz et al disclose a device for duplication and characterizing nucleic acids comprising a chamber support, a chamber body on the support and a capillary gap intermediate the support and body, the gap being adapted to act as a single chamber for both the reaction (e.g. hybridization) and characterization (detection) of nucleic acids (e.g. Fig. 7A; Column 15, lines 9-34; and Column 19, lines 1-15 and Column 24, line 34-Column 25, line 41).

Lipshutz et al teach their device comprises the chamber, support and gap whereby a single chamber is formed for reaction and characterization of nucleic acids. They further teach their device comprises additional reaction chambers. However, a single chamber is formed for hybridization and detection of nucleic acids. Therefore, the device of Lipshutz et al is encompassed by the instant claim.

Regarding Claim 26, Lipshutz et al disclose their device wherein the chamber includes an optically permeable chip (i.e. transparent window, Column 19, lines 20-29).

Regarding Claim 27, Lipshutz et al disclose their detection area includes immobilized probes (Column 8, lines 23-42; Column 9, lines 30-35; and Column 9, lines 20-29).

Regarding Claim 28, Lipshutz et al disclose their immobilized probes include nucleic acids, peptides or proteins (Column 8, lines 23-42; Column 9, lines 30-35; and Column 9, lines 20-29).

Regarding Claim 29, Lipshutz et al disclose the device wherein the detection area is optically permeable (i.e. transparent window, Column 19, lines 20-29).

Regarding Claim 30, Lipshutz et al disclose the device wherein the capillary gap is temperature adjustable and flow controllable. The claim does not require that the device comprise means for temperature adjustment or flow control of the capillary gap. The claim merely requires that the capillary gap be adjustable and controllable. Lipshutz et al teach the temperature and flow within the gap is controlled (Column 27, line 37-Colunn 29, line 67). Therefore, Lipshutz et al teach the device as claimed.

Regarding Claim 31, Lipshutz et al disclose the device wherein the heating elements include nickel-chromium resistive heaters (Column 24, lines 53-67).

Regarding Claim 32, Lipshutz et al disclose the device of Claim 1 wherein the temperature adjustment means includes micorstructured sensors (Column 25, lines 7-10).

Regarding Claim 33, Lipshutz et al disclose the device wherein the heating elements include nickel-chromium resistive heaters (Column 24, lines 53-67).

Regarding Claim 34, Lipshutz et al disclose the device of Claim 1 wherein at least one of the chamber support and the chamber body include an optically permeable synthetic materials selected from the group consisting of nylon, Teflon, topaz, polycarbonate, polystyrene, PMMA and polymethane ethyl acrylate (Column 15, line 49-Column 16, line 2).

Regarding Claim 35, Lipshutz et al disclose the device of Claim 1 wherein the chamber includes additional sealing surface adapted to releasable connect to the support (e.g. Column 4, lines 55-58; Column 7, lines 65-67; Column 16, lines 42-45; and Column 23, lines 1-27).

Regarding Claim 36, Lipshutz et al disclose the device of Claim 1 wherein the nucleic acid molecules include DNA or RNA (Column 9, line 30-Column 11, line 57).

Regarding Claim 39, Lipshutz et al disclose the device of Claim 18 wherein the optical detection includes at least one of transmitted-light fluorescence measurement, dark field fluorescence measurement, confocal fluorescence measurement, reflected-light fluorescence measurement, photometry and differential photometry (Column 12, line 63-Column 13, line 9).

Regarding Claim 40, Lipshutz et al disclose the device of Claim 1 wherein the capillary gap is adapted to provide almost simultaneous performance of characterization and reprocessing or conditioning (i.e. transparent window, Column 19, lines 20-29). The claimed "adapted to provide almost simultaneous performance...." does not define or describe structural components of the device. The transparent window of Lipshutz et al would provide for simultaneous observation and hybridization. However, because the claim recitation does not describe structural limitations of the device, the transparent window of Lipshutz is encompassed by the instantly claimed device.

The courts have stated that claims drawn to an apparatus must be distinguished from the prior art in terms of structure rather than function see *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). "[A]pparatus claims cover what a device is, not what a device does." Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1469, 15 USPQ2d 1525,1528 (Fed. Cir. 1990) (see MPEP, 2114).

Regarding Claims 41-43, Lipshutz et al disclose the device wherein various reactions are performed within a chamber e.g. pcr, transcription (Column 4, lines 1-45). The instantly claimed functions of the device i.e. pcr, reverse transcription, digestive process do not define or describe structural components of the device and therefore do not further limit the claimed device.

8. Claims 44-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Northrup et al (ups 6,521,181, filed 26 December 1996) of Sugarman et al (U.S. Patent No. 5,222,808, issued 29 June 1993).

Regarding Claim 44, Northrup et al disclose a device for duplicating and characterizing nucleic acids, the device comprising, a chamber body including sample inlet and outlet (#35 & 36) and a capillary gap intermediate the support and body (space within chamber #31), the gap consisting of a single chamber for both reaction and characterization of nucleic acids such that only the single chamber holds nucleic acids and wherein the inlet and outlet are only connected to the single chamber (Column 7, lines 20-44 and Fig. 3, 15 and 16). Northrup et al further teach the device having an inlet and outlet but does not teach the outlet is laterally offset and having a greater height.

However, Sugarman et al teach a reaction chamber having a gas reservoir (#59 and #60) within the capillary gap, in fluid communication with the gap and laterally offset from the reaction chamber and having a height that is greater than that of the capillary gap (Fig. 2). Sugarman et al further teach the gas reservoir, as constructed, provide for introduction of fluids into the capillary space and gases out of the space to provide "complete mixing" (Column 2, line 66-Column 3, line 14). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the vent of Northrup et al with the laterally offset vent of Sugarman et al. One of ordinary skill in the art would have been motivated to do so for the expected benefit of providing complete mixing in a simply designed chamber as taught by Sugarman et al (Column 2, line 66-Column 3, lines 14).

Regarding Claim 45, Northrup et al disclose the device wherein the gap includes means for reacting and characterizing the sample (i.e. transparent housing whereby light is directed into the chamber for heating and detecting fluorescence (Column 7, lines 20-44).

Regarding Claim 46, Sugarman et al teach the device wherein the gas reservoir is between the inlet (i.e. opening of inlet #50) and the capillary gap (#30-40; Fig. 2).

Regarding Claim 47, Northrup et al disclose the device wherein the single chamber is free of fluid channels to move nucleic acids to a subsequent reaction and characterization chamber (Column 7, lines 37-44 and Fig. 3).

9. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Woudenberg et al (U.S. Patent No. 6,126,899, filed 2 April 1997) or Lipshutz et al (U.S. Patent No. 5,856,174, issued 5 January 1999) in view of Sugarman et al (U.S. Patent No. 5,222,808, issued 29 June 1993) as applied to Claim 1 above and further in view of McBride et al (U.S. Patent No. (6,296,752, filed 4 June 1999) as defined by Academic Press Dictionary of Science and Technology (Academic Press, San Diego, 1992, page 1768)

Regarding Claims 6 and 7, the devices of Lipshutz et al and Woudenberg et al are discussed above. They do not teach the a quadrupole system comprising electrodes of gold-titanium.

However, electro-osmotic flow provided by gold-titanium electrodes was well known in the art at the time the claimed invention was made as taught by McBride et al who teach that improved electrodes for providing electro-osmotic flow comprise gold and titanium (Column 4, lines 1-16) wherein their electrode device comprises multiple electrodes providing a distribution of magnetic poles (Column 3, lines 34-55). Furthermore, Academic Press Dictionary of Science and Technology defines a distribution of magnetic poles as a quadrupole. Therefore, the multiple electrode device of McBride et al is a quadrupole system as defined by the Academic Press Dictionary.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the multiple gold-titanium electrodes of McBride et al to the

electrodes of Lipshutz et al or Woudenberg et al based on the improved teaching of McBride et al (Column 4, lines 1-16).

10. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lipshutz et al (U.S. Patent No. 5,856,174, issued 5 January 1999) in view of Sugarman et al (U.S. Patent No. 5,222,808, issued 29 June 1993) or Woudenberg et al (U.S. Patent No. 6,126,899, filed 2 April 1997) as applied to Claim 1 above and further in view of Atwood et al (U.S. Patent No. 5,475,610, filed 20 April 1992).

Regarding Claim 11, the devices of Lipshutz et al and Woudenberg et al are discussed above. They do not teach the reaction chamber comprises a conical recess. However, it was well known in the art at the time the claimed invention was made that the preferred surface for PCR reactions comprise conical recesses as taught by Atwood et al (Column 12, lines 28-47). Atwood et al further teach that conical recesses provide very tight temperature control for all samples and within each sample throughout the PCR cycles (Column 12, lines 40-47). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the conical recess of Atwood et al to the PCR reaction chamber of Lipshutz et al or Woudenberg et al thereby providing means for very tight temperature control for the expected benefit of controlling temperature of each sample throughout the PCR cycles as taught by Atwood et al (Column 12, lines 40-47).

11. Claim 16, 17 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lipshutz et al (U.S. Patent No. 5,856,174, issued 5 January 1999) in view of Sugarman et al

(U.S. Patent No. 5,222,808, issued 29 June 1993) or Woudenberg et al (U.S. Patent No. 6,126,899, filed 2 April 1997) as applied to Claim 1 above and further in view of Fodor et al (U.S. Patent No. 5,744,101, issued 28 April 1998).

Regarding Claims 16 and 37, the devices of Lipshutz et al and Woudenberg et al are discussed above. They do not specifically teach the probes are immobilized through spacers. However, Fodor et al do teach their probes are immobilized through spacers (i.e. linkers) and they teach a motivation to immobilize through spacers i.e. degree of probe-target binding is dependent on the presence of spacers (Column 18, lines 42-67). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the spacers of Fodor et al to the immobilized probes of Lipshutz et al or Woudenberg et al to thereby maximize probe-target binding as taught by Fodor et al (Column 18, lines 39-41).

Regarding Claim 17, Lipshutz et al teach the device wherein proteins are immobilized (Column 8, lines 39-42) but they do not teach the detection area comprises probes in the form of spots. However, detection areas (arrays) comprising spots of protein probes were well known in the art at the time the claimed invention was made as taught by Fodor et al who teach the peptide array provide a tool for high-density peptide-specific antibody recognition (Column 8, line 61-Column 9, line 30). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the peptide probes of Fodor et al to the detection area of Lipshutz et al to thereby provide for high-density antibody screening for the expected benefits of determining relative binding affinity between a plurality of peptides simultaneously as taught by Fodor et al (Column 2, lines 44-49).

Regarding Claim 38, Lipshutz et al teach the device wherein the proteins included receptor molecules e.g. antibodies (Column 8, lines 36-42).

Conclusion

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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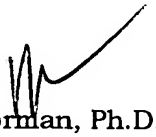

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